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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/348,815	07/08/1999	HAODONG LI	PF126P1D1	5784

22195 7590 01/29/2002

HUMAN GENOME SCIENCES INC  
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EXAMINER

ZARA, JANE J

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 01/29/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/348,815

**Applicant(s)**

LI, HAODONG

**Examiner**

Jane Zara

**Art Unit**

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-29,33-36,39,40,43,44,47-49,59-67,72-74,77,78,81,82,85 and 86 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21,22,24,26,28,59,60,62,64 and 66 is/are allowed.
- 6) ☒ Claim(s) 23,25,27,29,33-36,39,40,43,44,47-49,59,61,63,65,67,72-74,77,78,81,82,85 and 86 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

File

Application/Control Number: 09/348,815

Page 2

Art Unit: 1635

### DETAILED ACTION

This Office action is in response to the communication filed November 21, 2001, Paper No. 16.

Claims 21-29, 33-36, 39, 40, 43, 44, 47-49, 59-67, 72-74, 77, 78, 81, 82, 85 and 86 are pending in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### *Response to Amendments and Arguments*

##### Withdrawn Rejections

Rejection of claims 21, 26, 28, 59 and 64 under 35 U.S.C. 112, first paragraph, is withdrawn in light of Applicants' arguments filed November 21, 2001, Paper No. 16.

Rejection of claims 22, 24, 26, 60 and 62 under the judicially created doctrine of obviousness-type double patenting is withdrawn in light of the terminal disclaimer filed November 21, 2001, Paper No. 17.

##### Maintained Rejections

R.T.  
11/21/02

Claims 23, 25, 27, 29, 33, 36, <sup>39</sup>40, 44, 48, <sup>49</sup>61, 65, 67, 74, 78, 82 and 86 are rejected under 35 U.S.C. 112, second paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim, for the reasons set forth in the Office action mailed January 18, 2001, Paper No. 11.

Art Unit: 1635

Applicant's arguments filed November 21, 2001 have been fully considered but they are not persuasive. Applicants argue that the rejection made is inappropriate because the claims recite the limitations of the claims from which they depend, but also comprise a heterologous sequence. Contrary to Applicants' assertions, however, the language of the claims is not consistent with this interpretation. The claims, as written, embrace any amino acid sequences which are heterologous to SEQ ID NO: 2, or portions thereof as indicated. If Applicant intends to claim polypeptides comprising SEQ ID NO: 2 and further comprising a heterologous polypeptide fused to the polypeptide of SEQ ID NO: 2 (i.e. as in claim 53 of parent USPN 5,945,300), then the claims should be amended appropriately.

Claims 23, 25, 27, 29, 33-36, 43, 44, 47, 48, 59, 61, 63, 65, 67, 72-74, 77, 78, 81, 82, 85 and 86 are rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth in the Office action mailed January 18, 2001, Paper No. 11.

Applicant's arguments filed November 21, 2001 have been fully considered but they are not persuasive. Applicants argue that the required written description for the claimed genus, comprising any isolated amino acid sequence heterologous to SEQ ID NO: 2 or the portions thereof which are listed in the claims, as well as any amino acid sequence which has at least 95% homology to SEQ ID NO: 2 or the portions thereof which are listed in the claims, is adequately provided in the instant application because the structural and functional characteristics of SEQ Id NO: 2 have been provided. Contrary to Applicants' assertions, the disclosure of the polypeptide sequence and functional activity of SEQ Id NO: 2 does not adequately describe a representative

Art Unit: 1635

number of polypeptides which are varied, such that 95% identity to SEQ Id NO: 2 remains and functional activity is maintained. No mutagenesis data has been provided. A single polypeptide sequence comprising SEQ Id NO: 2 has been provided, whereby functional activity has been provided. Therefore, the broad scope claimed is not enabled by the instant disclosure.

Applicants also assert that the examiner's interpretation of the claims, "homologues...comprising stimulation for cellular proliferation" is erroneous and therefore the enablement rejection should be withdrawn. Contrary to Applicants' assertions, a representative claim (claim 34) recites "An isolated polypeptide comprising...amino acid sequence that is at least 95% identical to ... amino acids 1 to 381 of SEQ Id NO: 2; ... wherein said polypeptide stimulates cellular proliferation." The claim reads on homologues (i.e. 95% identity homologues) to SEQ ID NO: 2 which comprise cellular proliferating activity. The scope claimed is not enabled by the instant disclosure since no reasonable number of homologues of SEQ Id NO: 2 have been disclosed whereby cellular proliferating activity is maintained.

Claims 23, 25, 27, 29, 33, 36, 40, 44, 48, 61, 63, 65, 67, 74, 78, 82 and 86 are rejected under 35 U.S.C. 102(b) as being by Purchio et al for the reasons set forth in the Office action mailed August 15, 2001, Paper No. 15.

Applicant's arguments filed November 21, 2001 have been fully considered but they are not persuasive. Applicants argue that the reference cited does not anticipate every element of the claims. Contrary to Applicants' assertions, the claims are drawn to amino acid sequences heterologous to SEQ ID NO: 2, or the portions thereof indicated, and Purchio teaches amino

Art Unit: 1635

acid sequences which are heterologous to SEQ Id NO: 2. The limitation of SEQ ID NO: 2 cannot be implied from the language of the claims as they are presently written.

***Allowable Subject Matter***

Claims 21, 22, 24, 26, 28, 59, 60, 62, 64 and 66 are allowed.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1635

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

**JZ**

January 25, 2002

  
**ANDREW WANG**  
**PRIMARY EXAMINER** 